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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/278,601 07/21/94 KNIFE

18M1/1002

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D DFC1363A

EXAMINER

CAPOTA, A

ART UNIT

PAPER NUMBER

13

DATE MAILED: 1806

10/02/96

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

**OFFICE ACTION SUMMARY**

☒ Responsive to communication(s) filed on 6/24/96

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 1-9, 12-22, 25-27, 29, 31, and 32 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-9, 12-22, 25-27, 29, 31 and 32 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit:

### **DETAILED ACTION**

1. Applicants' amendment was received 6/24/96. Claims 1-9, 12-22, 25-27, 29, 31, and 32 are pending.

2. All prior rejections have been withdrawn in view of applicants response.

3. Claims 1-9, 12-22, 25-27, 29, 31, and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising a HSV-1 or HSV-2 having a mutation in the ICP8 and ICP 28, does not reasonably provide enablement for all herpesviruses, nor any protein essential for replication, nor viruses encoding heterologous antigens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While the specification provides a working example of using a mutated herpes simplex, since the claimed invention encompasses a multitude of herpesvirus, and the herpesvirus family encompass virus with different pathogenicity and clinical signs one skilled in the art would be forced into undue experimentation to practice the claimed invention. Furthermore, since protein which differ in replication have a different mode of action and structure and the specification provides a limited disclosure of those gene essential for replication one skilled in the art would be forced into undue experimentation to practice the claimed invention. Finally since

Art Unit:

heterologous antigens are lethal to hosts and foreign antigens are known not to be expressed in a sufficient level or proper formation to be protective in a vaccine one skilled in the art would be forced into undue experimental to practice the claimed invention.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Anthony C. Caputa, whose telephone number is (703)-308-3995. The examiner can be reached on Monday-Thursday from 8:30 AM-6:00 PM. The examiner can be reached on alternate Fridays. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703)-308-0196.

Papers related to this application may be submitted to Art Unit 1806 by facsimile transmission. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The Fax number is (703)-308-4242.

Anthony C. Caputa, Ph.D.

September 30, 1996

  
ANTHONY C. CAPUTA  
PRIMARY EXAMINER  
GROUP 1800